Approved by the Head of the Chief Sanitary Anti-epidemic Office of the Ministry of Public Health of U.S.S.R. (V. Zhdanov) Jan. 30, 1954

ACADEMY OF MEDICAL SCIENCES OF U.S.S.R. Institute of Epidemiology and Microbiology Named After Gamaleya (Moscow)

INSTRUCTIONS

To the fulfillment of vaccinations of the people against brucellosis by the live dry vaccine "IEM APN USSR"

I. General information about the vaccine

- 1. Live, dry antibrucellosis vaccine which has been prepared according to the method worked out by the Institute of Epidemiology and Microbiology of the Academy of Medical Sciences of U.S.S.R., is used for the immunization of the population wit the purpose of prevention of the brucellosis disease.
- 2. The vaccine is a dried matter of the live vaccinal culture of the brucils of the cow type.
- 3. Live, dry vaccine is sent out in a glass soldered ampule. The time of suitability of the vaccine is 12 months from the day of its preparation.
- 4. On each ampule of the vaccine there should be a label placed with the infor mation about the institute which prepared the culture, the time of preparation, the name of the vaccine, number of series, number of state control, the number of doses of the vaccine in the ampule, and the time of suitability.
- 5. The vaccine must be stored in a dark, cocl place with the temperature not higher than 10°C (the storage of the vaccine under 0°C is permitted if there are no sharp changes in temperature).
- 6. To each ampule of the dry vaccine another ampule containing a sterile physiological solution is added for its dilution.

II. The order of solution of the vaccine and the technique of inoculation

1. Before using, each ampule with the dry vaccine is thoroughly checked over. In case of any even insignificant cracks, foreign bodies, the appearance of any coloring foreign to the vaccine and other defects, this ampule is declared as spoiled and is destroyed according to the instructions given in paragraph 3. In its exterior the dry vaccine must be a compact, white mass.

- 2. The vaccine is diluted directly before the inoculation with the sterilized physiological solution in accordance with the given number of doses of the vaccine in the named ampule (for example: 10 doses of vaccine are diluted with 10 cm of physiclogical solution).
- 3. The process of dilution is done under sterile conditions. The neck of the ampule with the vaccine or physiological solution is sawed on the upper part, then wiped with alcohol, and carefully, so that the solution does not warm up, is burned. The neck is broken off. The physiological solution, which is in a separate ampule, is sucked in through the needle into a sterilized springe and introduced in the volume of 2 cm3 into the ampule with the vaccine. The ampule is shaken until the vaccine is completely diluted. The produced microbic matter is sucked into the same syringe and introduced into the empule with the physiclogical solution. After a thorough mixing, the diluted vaccine is checked and in case of foreign bodies or unbreakable flakes, this ampule with the di ted vaccine is declared spoiled and destroyed by boiling or by the disinfectants (lysol 3%, carbolic acid 5%, chloramine 2%).
 - 4. It is categorically forbidden to prepare diluted vaccine for storage. The diluted vaccine which has not been used in the course of 4 - 5 hours is destroyed by the same method as the vaccine which has been declared spoiled,
 - 5. During the inoculations an open ampule should be thoroughly protected from any kind of polution.
 - 6. The diluted vaccine is introduced once under the skin of the shoulder or in the region under the scapula in the dose of 1 cm3.

The skin is cleaned with alcohol before the inoculation. For cleaning the skin it is forbidden to use disinfectants because they kill the vaccine.

Notice: Drops of the vaccine which accidentally fall on the floor or other objects must be removed by alcohol or disinfectants.

7. Adults are vaccinated by one dose of the vaccine (1 cm³), children from 10 to 15 years a half a dose of the vaccine is introduced (0.5 cm³), children from 7 to 10 years (in case of an obvious langer of infection) one third of the adult dose,

III. Reaction to the inoculations

1. The local and general reaction to the introduction of vaccine is insignificant or is lacking completel; .

Persons with negative caro-allorgic reactions who were sick with brucellosis once can have an expressed local and general reaction to the vaccine.

- 2. A local reaction to the vaccine arises from 24 to 48 hours in the form of reddening, an infiltrate which dies down in the course of 3 to 5 days.
- 3. The general reaction to the vaccine arises in the first 24 hours after the inoculation in approximately 3% of the cases and is expressed in indisposition, headache, and rising of the body temperature to 37.5° - 38°C.

4. Vaccinated patients, after 1 - 2 months from the inoculation, have positive serological and allergic reactions which are preserved (especially the allergic reactions) for about a year and longer.

IV, Selection of the patients subject to vaccinations

- 1. Inoculations are permitted for people with negative immunological reactions to brucellosis. The registering of the allergic reaction is done 24 to 30 hours after its setting.
- 2. In the fall-winter period, the time distant from lambing time (4 5 months before lawing time) the selection of people can be done according to the allergic reaction only.
- 3. In the period close to lambing time (2-3 months before lambing time) when there is the biggest possibility for the service personnel to encounter massive doses of the infect, the selection of the contingents is done by the complex method according to the allergy test and one of the serological reactions.
- 4. At the meat combines, slaughter houses and other enterprises working on the raw material which come from farms which are not quite safe in regard to brucellosi the selection of the contingents should be done by the complex method.

Counter-instructions to the vaccination V.

- 1. The presence of positive serological and allergic reactions to brucellosis.
- 2. The presence of clinical manifestations of brucellosis during the examination with negative serological and allergic reactions.
- 3. General counter-instructions: decompensated heart defect, acute and chronic disease of the kidneys, tuberculosis, pregnancy and lactation, clinically expressed acuice discuses.
- 4. The vaccination against brucellosis together with other inoculations is forbidden. Vaccinations against brucellosis are done not earlier than 10 days afte a previous vaccination and not later than 30 days before other inoculations.

VI. Revaccination

- 1. Revaccination is permitted after 10 12 months after vaccination only to persons with negative serological and allergic reactions. Revaccination is done only according to epizootiological and epidemiological deposition.
- 2, Kevaccination (first and repeated) is done with a half dose set for vaccination.
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